DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

BioTime Incorporated
Mr. David C. Furr
Principal Consultant
8708 Capehart Cove
Austin, Texas 78733

Re: K134037
Trade/Device Name: BioTime Premvia
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 7, 2014
Received: July 8, 2014

Dear Mr. Furr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K134037

Device Name
BioTime Premvia

Indications for Use *(Describe)*
Premvia is indicated for the management of wounds including: partial thickness, full-thickness, tunneling wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, donor skin graft sites, post-Moh's surgery, post-laser surgery, podiatric wounds, wound dehiscence, abrasions, lacerations, second degree burns, skin tears and draining wounds.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary Pursuant to 21 CFR 807.92

K134037

Date: July 2, 2014

1. Submitted By: BioTime, Inc.
1301 Harbor Bay Parkway
Alameda, CA 94502
510-521-3390

2. Contact: David C. Furr
FDC Services, LLC
8708 Capehart Cove
Austin, Texas 78733
512-906-9654

3. Product: BioTime *Premvia*™
Regulation – N/A
Classification – Unclassified
Product Code: KGN

4. Common/Trade Name: Dressing, Wound, Collagen
Premvia™

Description:

Premvia™ is a wound matrix supplied in a package containing sterile 3 lyophilized vials and 1 vial of sterile reconstitution solution. *Premvia*™ is a resorbable, viscoelastic hydrogel matrix that consists of modified glycosaminoglycan and collagen molecules that crosslink upon reconstitution and combination of the three sterile, lyophilized components: thiol-modified hyaluronan, thiol-modified gelatin, and polyethylene glycol diacrylate (Extralink). To create the hydrogel, each component is reconstituted with sterile saline solution (pH 6.8-7.2) and then mixed together.

Intended Use:

Premvia™ is indicated for the management of wounds including: partial-thickness, full-thickness, tunneling wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, donor skin graft sites, post-Moh's surgery, post-laser surgery, podiatric wounds, wound dehiscence, abrasions, lacerations, second degree burns, skins tears and draining wounds.

Technological Characteristics:

The product is a single use kit consisting of 4 components: Glycosil® (thiol-modified hyaluronan), Gelin® (thiol-modified gelatin), Extralink® (polyethylene glycol diacrylate, PEGDA), and a saline reconstitution solution (pH-adjusted Lactated Ringer's solution). The first three components are supplied in vials as pre-measured, sterile, and lyophilized solids that, when dissolved in the saline reconstitution solution (the 4th component) and mixed together, form a clear, transparent, and viscoelastic hydrogel matrix which can be used as a flowable wound dressing. The three lyophilized components, when reconstituted and combined will yield about 5cc of hydrogel.

Product testing has been done to assess the following characteristics:

- ISO 10993 Biocompatibility, including the following –
  - Ames Mutagenicity
  - Genotoxicity
  - Cytotoxicity
  - Implantation
  - Sensitization
  - Irritation
  - Systemic Toxicity
- EN 13726-1 Tests for primary wound dressings including the following–
  - Free Swell Absorptive Capacity
  - Fluid Affinity of Amorphous Hydrogel Dressings
  - Dispersion/Solubility of Hydrogel Dressings
- Cytocompatibility with human skin cells

Substantial Equivalence:

Premvia™ is substantially equivalent to the following cleared device:

INTEGRA™ Flowable Wound Matrix (K072113) - Integra LifeSciences Corporation

Premvia™ wound dressing is substantially equivalent to the INTEGRA Flowable Wound Matrix (K072113) since they have essentially the same:

- Indications for use – There are no significant differences in indications.
- Class of materials that compose each device - Both *Premvia*™ and Integra wound matrices are composed of collagen and glycosaminoglycan. *Premvia*™ is composed of porcine denatured collagen and hyaluronic acid (a glycosaminoglycan) which is crosslinked in situ. Integra is composed of crosslinked chondroitin sulfate (a glycosaminoglycan) and bovine collagen. Collagen or denatured collagen, glycosaminoglycan, or a combination of the two has also been used in a variety of other wound healing devices with the same classification (KGN).

- Delivery method (syringe) - *Premvia*™ and Integra Flowable Wound matrix are both rehydrated or reconstituted before use and mixed within a syringe before application. For both products the application syringe is used to apply directly within tunneled or undermined wounds or onto the surface of other more superficial as prescribed.
- Biocompatibilty and Properties – Both *Premvia*™ and Integra Flowable Wound matrix have been extensively tested and determined to be biocompatible. In addition, comparison testing was done to assess physical characteristics of hydrogel wound dressings. These properties include the dispersion, absorbance, and hydrating properties of gel or gel-like wound products. *Premvia*™ and Integra Flowable Wound matrices both act by providing moisture to the wound environment, providing important hydration for dry wounds that may accelerate healing, and both products are dispersible, meaning that unincorporated or unintegrated material may be removed when desired with irrigation or debridement. They also swell slightly in more moist environments, indicating a similar level of ability to absorb wound exudate.
- Both products are capable of providing a matrix for cells and vascular integration.

Conclusion:

Our concusion is that *Premvia*™ and Integra Flowable Wound matrix are substantially equivalent since they have equivalent indications, presentation, chemistry, and function. No significant differences exist that would affect equivalence.